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| 10/523,479 | 09/16/2005 | Magdalene M. Moran | 110313.138US2 | 6126 |
| 23483 | 7590 | 01/29/2009 | EXAMINER | |
| WILMERHALE/BOSTON | | | MONTANARI, DAVID A | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/523,479 | Applicant(s) MORAN ET AL. | |
| | Examiner David Montanari | Art Unit 1632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicants arguments and amendments filed on 11/5/2008 have been entered.
2. Claim 5 is amended.
3. The rejection of claim 5 under 35 USC 112, first paragraph, scope of enablement is withdrawn in view of Applicant's amendments to the claim.
4. Claim 5 is examined in the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 5 is rejected under 35 U.S.C. 102(e) as being anticipated by Chang et al. (U.S. Patent 6,183,751).

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The isolated nucleic acid of the claimed invention is broadly interpreted to encompass a fragment of the human or mouse CatSper3 protein, its transmembrane domains, extracellular loop and pore region. There is no requirement in the claimed invention that a function be ascribed to the claimed nucleic acid and in this respect any span of nucleotides that would encompass two or more nucleotides of the claimed invention is interpreted to anticipate the claimed invention.

Chang et al. teach that SEQ ID NO: 20 in U.S. Patent 6,183,751 comprises the span of nucleotide bases TCATCCTGCT corresponding to nucleotides 19901-19908. In the instant specification SEQ ID NO: 1 teaches that at nucleotide bases 617-625 the bases are TCATCCTGCT. Since the claimed invention does not recite what portion of the human or mouse CatSper3 protein must be at least 95% identical and the claimed nucleic acid is broadly interpreted to encompass a fragment, the span of nucleotide residues taught in SEQ ID NO: 20 by Chang et al. above is considered anticipatory over the claimed isolated nucleic acid.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 5 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record in the office action mailed on 5/5/2008.

When the claim is analyzed in light of the specification, the instant invention encompasses any isolated nucleic acid sequence that encodes a polypeptide having an amino acid sequence identity with a polypeptide encoding a human or mouse CatSper3 protein. However, the specification teaches only the nucleotide sequences disclosed in SEQ ID NO's 1 (human) and 3 (mouse) with regard to Catsper3. In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, only SEQ ID NO: 1 and SEQ ID NO: 3 are the only species whose complete structure is disclosed. The specification does not provide any disclosure as to what the complete structure would be of any isolated nucleotide sequence that would encode a CatSper3 protein. The specification teaches structural analysis of only SEQ ID NO's 1 and 3. Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. other than nucleotide sequence), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case, the only characteristic described, is the nucleotide sequence and functional domains present in SEQ ID NO's 1 and 3. The specification does not teach any other identifying characteristic or any other related sequences that would guide the artisan to contemplate other nucleotide sequences that would encode for a CatSper3 protein.

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Applicants' attention is directed to the decision in *In re Shokal*, 113, USPQ 283 (CCPA 1957) wherein is stated:

It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim, *In re Soll*, 25 C.C.P.A. (Patents) 1309, 97, F.2d 623, 38 USPQ 189; *In re Wahlforss et al.*, 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such a number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as halogens, consisting of four species, a reduction in practice of three, or perhaps even two, might server to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

In conclusion, this limited information is not deemed sufficient to reasonably convey to one skilled in the art that applicant is in possession of any nucleotide sequence that encodes a CatSper3 protein other than those sequences disclosed in SEQ ID NO's 1 and 3.

Response to Arguments

Applicants Arguments

Applicants argue in amendment filed 11/5/2008 that without acquiescing to this rejection, and solely to expedite prosecution, claim 5 has been amended. Applicants argue that amended claim 5 is now drawn to an isolated nucleic acid encoding a polypeptide having at least 95% amino acid sequence identity with a polypeptide selected from the group consisting of: a human or mouse CatSper3 protein; at least a transmembrane domain of a human or mouse CatSper3

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protein; at least an extracellular loop of a human or mouse CatSper3 protein; and at least a pore region of a human or mouse CatSper3 protein. This argument is not persuasive.

Response

While Applicant has amended claim 5 to recite that it is now drawn to an isolated nucleic acid having 95% identity with a human or mouse CatSper3 protein, its extracellular loop, pore region and transmembrane domains, Applicants have not addressed the specific issues set forth in the previous written description rejection. Specifically, the isolated nucleic acid has not been sufficiently described, other than its corresponding SEQ ID NO, such that it would be apparent that Applicant is in possession of any nucleotide sequence that would encode a human or mouse CatSper3 protein, its extracellular loop, pore region and transmembrane domain. The claims, while being drawn to 95% identity, also encompass fragments of the human or mouse CatSper3 protein and its functional domains. Applicant has not provided any teaching in their specification that would guide the skilled artisan to contemplate any isolated nucleic acid sequence or fragment that would encode a human or mouse CatSper3 protein other than the disclosed SEQ ID NO's: 1 and 3. Thus it is maintained that Applicant has not met the description requirement for the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 5 is unclear with respect to the metes and bounds of a human or mouse CatSper3 protein. Claim 5 is drawn to an isolated nucleic acid encoding a polypeptide having at least 95% amino acid sequence identity with a human or mouse CatSper3 protein, at least a transmembrane domain of said proteins, at least an extracellular loop of said proteins and at least a pore region of said proteins. However, while claim 5 is limited to 95% amino acid sequence identity, it is unclear what amino acid sequences are encompassed by a human or mouse CatSper3 protein since the claimed invention encompasses any amount of amino acids, from just a few up to full-length, within either the human or mouse CatSper3 protein. The claimed isolated nucleic acid recites no reference point such that the skilled artisan would clearly understand which amino acids would comprise 95% amino acid identity with a human or mouse CatSper3 protein. Whereas, the specification has disclosed specific nucleotide and amino acids sequences in SEQ ID NO's: 1-4 such that a reference point could be determined based upon the sequence disclosure, the claims do not recite said SEQ ID NO's such that the skilled artisan could determine the metes and bounds of the claimed isolated nucleotide sequence.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is (571)272-3108. The examiner can normally be reached on M-Tr 8-6.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David A. Montanari

AU 1632

/Peter Paras, Jr./

Supervisory Patent Examiner, Art Unit 1632